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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/612,240	07/01/2003	Li-Xi Yang	056367-0200	3322

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EXAMINER

OWENS, AMELIA A

ART UNIT	PAPER NUMBER
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1625

DATE MAILED: 01/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/612,240	Applicant(s) YANG, LI-XI	
	Examiner Amelia A. Owens	Art Unit 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 October 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,8,11-15,22-24 and 57-59 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1,8,14,15,22 and 23 is/are allowed.
- 6) ☒ Claim(s) 11,12,24 and 57-59 is/are rejected.
- 7) ☒ Claim(s) 13 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. Claims 57-59 are added. Claims 1,8,11-15,22-24,57-59 are pending.

Claim Rejections - 35 USC § 102

2. The rejection of claims 1,8,14,22 under 35 USC 102(b) over Nagao et al is dropped as the claims have been amended.
3. Claims 11,57 are rejected under 35 U.S.C. 102(b) as being anticipated by Fischer et al CA 133:9081 that teach species according to the invention. See RN254893-96-4. The other species are not included as the pyrolysis is fully saturated.
4. Claims 11,12,57 are rejected under 35 U.S.C. 102(b) as being anticipated by Lie Ken Jie et al CA 132:3273 (already of record, cited 7/20/2005 on PTO-892) that teach species according to the invention. See RN 251109-11-2.
5. Claims 11,12,57 are rejected under 35 U.S.C. 102(b) as being anticipated by Pan et al CA 129:175488 that teach species according to the invention. See RN 211615-64-4; 211615-65-5.
6. Claims 11,12,57 are rejected under 35 U.S.C. 102(b) as being anticipated by Wang et al CA 127:149030 that teach species according to the invention. See RN 193404-42-1.

For above paragraphs 3-6, claims not included in the rejections recite limitations outside the scope of the reference.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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7. Claims 11,12,57-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pan et al CA 129:175488 that teach species according to the invention. See RN 211615-64-4; 211615-65-5.

8. Claims 11,12,57-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wang et al CA 127:149030 that teach species according to the invention. See RN 193404-42-1.

For above paragraphs 7 and 8, one of ordinary skill in the art would thus be motivated to prepare compounds from under the Pan et al AND the Wang et al genus in order to obtain additional beneficial antitumor agents. Also, one of ordinary skill in the art would be motivated to prepare compounds structurally similar to those of Pan et al AND Wang et al in the expectation of obtaining a useful compound to treat tumors as compounds structurally similar in structure are expected to have similar properties. The level of skill in the art is further reflected in In re Lohr 137 USPQ 548 at 549 (CCPA 1963), and in In re Payne 204 USPQ 249 at 254 (CCPA 1979).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 24 and 59 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating breast cancer, does not reasonably provide enablement for treating colon cancer. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue". These factors include 1) the breadth of the claims, 2) the nature of the invention, 3) the state of the prior art, 4) the level of one of ordinary skill, 5) the level of predictability in the art, 6) the amount of direction provided by the inventor, 7) the existence of working examples, and 8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. In re Wands, 858 F.2d 731,

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737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). All of the factors have been considered but only the most relevant will be discussed below.

The claims are directed to a method of treating breast or colon cancer using the compounds of claim 1 or the compounds of claim 11. The state of the art is that the podophyllotoxin derivatives, etoposide in particular, are known to treat breast cancer. See Weller et al, 21-day oral Etoposide for metastatic breast cancer: a phase II study and review of the literature, PMID: 10857889. Structurally similar compounds would be expected to have similar properties. Thus, the skilled artisan would expect the claimed podophyllotoxin derivatives to treat breast cancer.

Compounds according to the invention have been made. The data in the specification is noted. There is no absolute predictability despite the high level of skill in the art. In the instant case, the instantly claimed invention is highly unpredictable given that cancer treatment has been known to be compound and disease specific, that is a particular compound or class of compounds can be useful in treating a particular type or class of cancer. Thus, a compound that treats breast cancer may not treat colon cancer.

Thus, the specification fails to provide sufficient support of the broad use of the compounds of claim 1 for the treatment of colon cancer.

Claim Objections

10. Claim 13 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Allowable Subject Matter

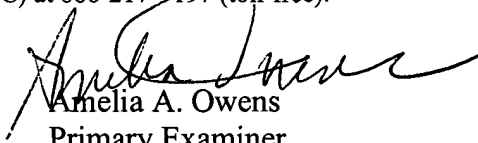
11. Claims 1,8,14,15,22,23 are allowed. The prior art neither teaches nor suggests the claimed compounds or their use. In the absence of any evidence or apparent reason why the claimed compounds do not possess the disclosed utility, the allegation of utility in the specification must be accepted as correct. In re Kamal et al, 158 USPQ 320; Ex parte Krenzer, 199 USPQ 227.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amelia A. Owens whose telephone number is 571-272-0690. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia J. Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Amelia A. Owens
Primary Examiner
Art Unit 1625